



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/056,734 | 01/25/2002 | A. Robert Spitzer | 0594.00034 | 9911 |
| 48924 | 7590 | 03/23/2007 | EXAMINER | |
| KOHN & ASSOCIATES PLLC 30500 NORTHWESTERN HWY STE 410 FARMINGTON HILLS, MI 48334 | | | LIU, SUE XU | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1639 | | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/23/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 10/056,734 | SPITZER, A. ROBERT | |
| Examiner | Art Unit | | |
| Sue Liu | 1639 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 December 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-22 and 28-32 is/are pending in the application.
4a) Of the above claim(s) 1-21,28,29,31 and 32 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 22 and 30 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application
6) Other: _____.

DETAILED ACTION

Claim Status

1. Claims 23-27 have been cancelled as filed on 12/29/06.
Claims 1-22 and 28-32 are currently pending.
Claims 1-21, 28, 29, 31 and 32 have been withdrawn.
Claims 22 and 30 are being examined in this application.

Election/Restrictions

2. Applicant elected without traverse to prosecute the invention of group II, claims 22, 25, 27, and 30, as acknowledged in the previous Office action mailed 4/11/05 at p. 3, para 6.

Priority

3. This application claims benefit of provisional application 60/264,413 filed on 01/26/2001, and provisional application 60/302,799 filed on 7/3/2001.

Claim Objections / Rejections Withdrawn

4. In light of applicant's amendments to the claims, the following objection to the claims is withdrawn:
 - A.) Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

5. In light of applicant's amendments to the claims to recite "pharmaceutically acceptable carrier within" the suppository, the following claim rejections are withdrawn:

A.) Claims 22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. (New Matter rejection).

B.) Claims 22, 25 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and/or using a suppository composition comprising valproate, valproate salts, or sodium valproate, and other pharmaceutical carriers, does not reasonably provide enablement for making and/or using a suppository consisting of only valproate, valproate salts, or sodium valproate.

C.) Claims 22, 25 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

D.) Claims 22 and 25 are rejected under **35 U.S.C. 102(b)** as being anticipated by Bauer et al (US 4,558,070; 12/10/1985).

Claim Objections / Rejections Maintained

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Hoogdalem and Raskin

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Hoogdalem et al (Clin. Pharmacokinet. Vol. 21 (1): 11-26; 1991), in view of Raskin (The Western Journal of Medicine. Vol. 161: 299-302; 1994). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 10/2/06, at p. 13+.

Discussion and Answer to Argument

8. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant argues that because "there is no teaching of the use of a suppository for treating migraines in either reference", there is no motivation to combine the references. (Reply, pp. 9-10; bridging para).

Applicant is respectively directed to the previous Office action (mailed 10/2/06; p. 14; especially para 1 and 3) for discussion of motivation to combine.

Applicants also argue that the references only teaching "preventing, not treating migraine". (Reply, p. 10, para 1).

Applicants have made the above allegation without any supporting evidence. Applicants are respectively directed to the previous Office action (mailed 10/2/06; pp. 13-14) for discussion of the references' teachings (such as "treating" migraine).

Applicant also argues that due to the lack of teaching of using suppository comprising valproate to treat migraine despite the early publication of the references, "unexpected results" would be established for the instant claimed invention. (Reply, p. 10, para 1).

In response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). In this case, applicants have not shown that the art has tried and failed to solve the problem of using valproate containing suppository to treat migraine.

Sorensen and Murata

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen (Acta Neurologica Scandinavica. Vol. 78: 346-348; 1988), in view of Murata (US 5,500,221; 3/19/1996; cited in the previous Office action, mailed 2/21/06). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 10/2/06, at p. 14+.

Discussion and Answer to Argument

10. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant argues "that no prior art reference discloses a medicine suppository consisting essentially of a medication selected from the group consisting ... for treating migraine" (emphasis added; Reply, p. 10, para 3).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a composition consisting essentially of valproate, etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Contrary to applicant's assertion, the Murata reference teaches a suppository comprising valproate, which reads on the claimed suppository of instant claim 30.

Applicants also argue that the references only teaching "preventing, not treating migraine". (Reply, p. 10, para 3).

Applicants have made the above allegation without any supporting evidence. Applicants are respectively directed to the previous Office action (mailed 10/2/06; pp. 13-14) for discussion of the references' teachings (such as "treating" migraine).

Applicant also argues "the Murata, et al. patent does not disclose the suppository without the inclusion of additional compositions", and thus the reference's teaching does not read on the instant claim (Reply, p. 10, para 3).

However, the instant claim (Claim 30) is not drawn to a suppository consisting only of valproates "without inclusion of additional compositions". Thus, the combination of the said references is obvious over the instant claimed invention.

New Claim Objections/Rejections

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 30 recite the phrase “in a pharmaceutically acceptable carrier” in lines 3-4, which is unclear. It is not clear if each of the recited “medication” (i.e. valproate, sodium valproate, or valproate salts) is “in a pharmaceutically acceptable carrier”, or if only “valproate salts” are “in a pharmaceutically acceptable carrier.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,500,221 (Murata et al; cited previously). This rejection is necessitated by applicant’s amendment to the claim.

The instant claims briefly recite a medicine suppository for treating a migraine consisting of an effective amount of a medication selected from the group consisting of valproate, sodium valproate, and valproate salts in a pharmaceutically acceptable carrier within a suppository for the treatment of a migraine headache. The recitation “for the treatment of a migraine headache” is construed as intended use.

Murata et al disclose suppository preparation comprising a therapeutically effective amount of an acidic drug or a pharmaceutically acceptable salt thereof which can be absorbed by rectal administration, wherein the acidic drug is sodium valproate (i.e., see claim 1) (reads on the instant claim 22 medicine suppository consisting of valproate and a pharmaceutically acceptable carrier. Murata et al teach that the suppository preparation contains other additives, such as absorption enhancers, preservatives, stabilizers, surfactants, perfumes, pigments, purified water, and various polymers (i.e., see column 3) (reads on the pharmaceutical acceptable carrier of claim 22). The reference clearly anticipates the claimed invention.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1639

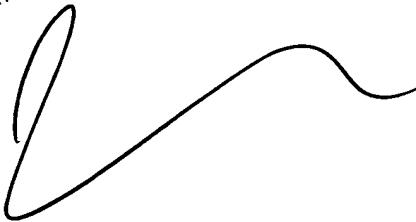
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON EPPERSON
PRIMARY EXAMINER



SL
Art Unit 1639
3/13/2007